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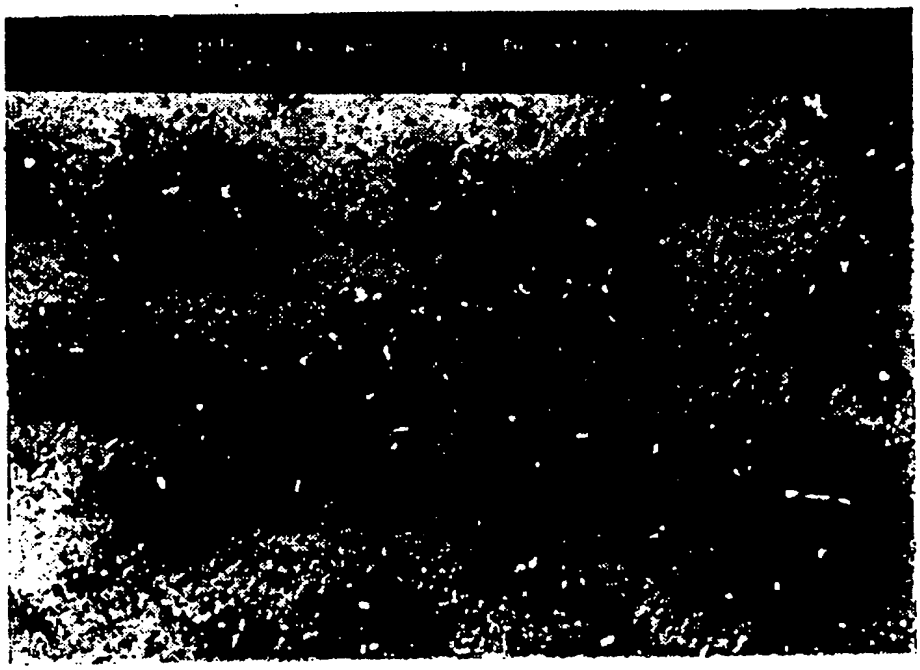
(57) Abstract

Many medical implants have roughened surfaces that promote cell, bone or tissue adhesion as well as the adhesion of bone cement, for better affixing of the implants in the body. The roughened surfaces should be free of particulates, such as commonly arise from the blasting of implant surfaces with particulates to produce a desired surface finish. A method of producing implants with implant surfaces free of such particulates is to blast the implant surface with a biocompatible liquid, such as water, under high pressure. Under certain circumstances, a solvent may contain particulates that assist in producing the roughened surface, and the particulates are dissolved, sublimated or vaporized from the implant surface, leaving no particulate residue.



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MEDICAL IMPLANTS

The invention relates to medical implants, of all kinds, with roughened surfaces that promote cell, bone or tissue adhesion as well as the adhesion of bone cement, sometimes used to affix certain implants in place in the body. Further, the roughened surface implants of the invention are free of particulates, such as commonly arise from the blasting of implant surfaces with particulates to produce a desired surface finish.

In the final stages of the preparation of medical implants, the implants are sometimes blasted with a solid medium, such as alumina, silica (glass), or silicon carbide, to roughen the surfaces. This roughening process is designed to enhance the attachment of bone, cell, tissue, or bone cement, depending upon the implant application.

Roughened surfaces may advantageously be applied to a variety of medical implants, including orthopedic implants, dental implants, cardiovascular implants, and the like. For orthopedic and dental implants, the rough surface facilitates interlocking of the implant with bone, tissue or bone cement. This tends to minimize micromotion, a phenomenon that results in loosening of the implant. Roughened surfaces on cardiovascular implants promote desirable cell attachment and which has been linked with a reduction in thrombus response.

Blasting and shotpeening implants with solid media also introduce residual compressive stresses on the surface of the implants, thereby improving the fatigue strength of the device. To the extent that the surfaces can also be roughened by these treatments, fatigue strength is reduced. Thus, fatigue strength increases with

greater residual surface compressive stresses and decreases with increase in surface roughness.

Regardless of the rationale for blasting implant surfaces with particulate solid media, the commonly used blasting process can result in contamination of the implant surface with fragments of the particulates. Typically, the blasting medium is carried by compressed air and is harder than the implant so that fragments of the blasting medium become embedded in or attached to the surface of the implant. Unless this residual debris is removed, it can be released into the body following implantation and cause adverse cell and tissue reactions. Even when the blasting medium is of a biocompatible material, adverse cell and tissue reactions have been observed in the presence of particulate debris. This is known as "particulate disease" and has been observed as being caused by ingestion of these particulates by macrophages which subsequently exhibit a foreign body response and release certain enzymes that cause lysis or death of bone cells. This in turn can lead to loosening of the implant and failure of the surgery. Particulate debris may also potentially migrate into spaces between articulating surfaces of a total hip or knee joint prosthesis thereby causing accelerated three-body abrasive wear. This abrasion process can also increase the generation of polymer or metal debris from the joint prosthesis and further accelerate adverse cell and tissue response. Not only does this tend to reduce the useful life of the implant, which is abraded away, but it also results in inflammation of joints and particulate disease.

U.S. patent 5,057,108 relates to a surface treatment process for stainless steel orthopedic implant devices. In this process, the stainless steel implant is first blasted with stainless steel shot to cold work the surface and introduce residual compressive stresses. The

steel shot blasting treatment is then followed by blasting with smaller glass beads, represented as improving the fatigue properties of the surface by cold working those areas not covered by the larger steel shot. It is also represented that glass bead blasting cleans the surface of any residual steel shot that may have transferred to the implant surface. After these two steps, the surface is electropolished and passivated by immersion in nitric acid solution. However, even if the glass beads remove stainless steel contamination, the implant surface may then contain imbedded or loosely attached debris from the glass beading process. Electropolishing or passivation would not remove this cross-contamination particulate debris which would ultimately be released into the body of a patient potentially causing adverse cell reactions.

Similarly, U.S. patent 5,251,468 describes a method of blasting the surfaces of orthopedic implants with media including calcium phosphate ceramics, phosphate glass compositions, bioabsorbable glass, partially bioabsorbable glass, bioabsorbable ceramics, and partially bioabsorbable ceramics. The purpose of the blasting is to enhance the fatigue and corrosion properties of the implant and to remove residual carbon from porous surfaces of an implant. While it is represented that, because the particles are made of bioactive material they are not a cause for concern when remaining as a residue on the porous surface, it is nevertheless well known that particulate disease has been observed regardless of the nature of the debris. Thus, even the supposedly harmless bioactive blasting materials of this patent can cause particulate disease or accelerated three-body abrasive wear of total joint implants.

U.S. patent 5,236,459 describes a method in which a high pressure liquid jet is used to form cone shaped cavities in an implant

on spacings to provide for intercommunication between the respective cavities. However, in order for these apertures to communicate "below the surface of the implant," significant amounts of material need to be removed and deep cavities formed. This would cause significant reduction in the fatigue strength of the implant.

U.S. patent 5,258,098 describes a chemical milling process to create an attachment surface for increasing adhesion between two objects or materials. However, the chemical etchants which are used for this purpose are strong acids which are hazardous to work with and create environmental concerns at the time of disposal after use. Further, if any of these acids remain on the implant when it is implanted, they can cause damage to the adjacent bone and tissue.

U.S. patent 5,226,260 describes a method which includes the step of eroding elastomer from a medical electronic lead using particulate abrasive. However, the patent states that the particulate should be such as to avoid scratching of the embedded metal. The patent does not address how to roughen the surface of metallic and other implants for enhanced bone or bone cement attachment.

International patent application WO 94/16836 is directed toward a method of cleaning roughened or porous-coated medical implant surfaces that contain loosely-adherent debris and particles. The disclosed method involves blasting the surface of the implant with biocompatible particulate solids in a manner which dislodges the debris and particles. This method, however, only cleans the surface and does not itself roughen the surface or produce residual compressive stresses in the surface.

There is therefore a perceived need for implants with roughened surfaces that will enhance the attachment of cells, bone, tissue or bone cement, without introducing particulate debris into the body. There is also a need for efficient methods for producing such medical implants.

Accordingly, there is provided a method of producing a medical implant comprising the step of:

blasting at least a portion of an outer surface of the implant with a medium comprising a biocompatible liquid.

The invention is directed to a method of forming medical implants, of all kinds, with roughened surfaces for enhanced cell and bone cement attachment, and implants with such surfaces. The implant surfaces may have residual compressive stresses and are free of particulate debris, thereby reducing or eliminating the potential for particulate disease and curtailing the potential for accelerated three-body abrasive wear caused by particulate debris.

The preferred methods for producing medical implants according to the invention include subjecting surfaces of the medical implant to a high pressure jet of a biocompatible liquid. The impact pressure of the solvent on the implant surface should be sufficient to remove machining debris and also roughen the surface for bone, cell, tissue or bone cement adhesion. It may also introduce residual compressive stresses into the surface to enhance fatigue strength.

In alternative embodiments of the preferred method, the biocompatible liquid may include a biocompatible, solid particulate medium, such as non-toxic soluble salts, non-toxic particulate solids

that deliquesce, sublimate or vaporize, but that are sufficiently hard to provide an effective impact on the implant surface to create a roughened surface for bone, tissue, cells or bone cement adhesion.

After the implant surface is blasted with the biocompatible liquid containing biocompatible particulate solids described above, the implant may optionally be subjected to ultrasonic cleaning or flushing with a biocompatible liquid medium to remove or dissolve any blasting residue.

Finally, the roughened implant surface may be further treated to provide a chemically passive surface. Such passivation techniques include dipping in solutions of nitric acid, or passivating by immersion in solutions of non-aggressive oxyanions, as detailed in our U.S. patent 5,211,663, which is hereby fully incorporated by reference. The process parameters used during the blasting process may be adjusted depending upon whether roughening the surface for enhanced cement, bone, tissue or cell attachment is the primary objective, or improving the fatigue strength by introducing residual compressive stresses is the primary objective. If roughening the surface is the primary objective, more aggressive blasting methods, e.g., higher blasting pressure, greater duration of blasting and/or smaller blasting nozzle distance, may be employed. If improvement in fatigue strength is the primary objective, roughening of the surface should be minimized by judicious selection of the operating variables since increased surface roughness causes reduction in fatigue strength. If solid blasting media are being used, this may involve using more spherical media and/or denser media which would resist fragmentation and minimize roughening of the substrate.

Figure 1 is a photomicrograph of a surface of cobalt-chrome-molybdenum alloy disk (C-7) at 50 times magnification after being hydroblasted with water only. Figure 2 is a photomicrograph of the surface of cobalt-chrome-molybdenum alloy femoral knee component at 50 times magnification, after blasting with alumina grit.

Figure 3 is a photomicrograph at 200 times magnification of a water jet blasted cobalt-chrome-molybdenum alloy disc (C-7).

Figure 4 is a photomicrograph at 200 times magnification of an alumina grit blasted cobalt-chrome-molybdenum knee femoral component.

Figure 5 is a photomicrograph at 50 times magnification of the surface of a water jet blasted Ti-6Al-4V alloy disc (T-4).

Figure 6 is a photomicrograph at 50 times magnification of an alumina grit blasted Ti-6Al-4V knee tibial component.

Figure 7 is a photomicrograph at 200 times magnification of the surface of a water jet blasted Ti-6Al-4V alloy disc (T-4).

Figure 8 is a photomicrograph at 200 times magnification of an alumina grit blasted Ti-6Al-4V knee tibial component.

Figure 9 is a photomicrograph at 50 times magnification of the surface of a water jet blasted aluminum disc (A-7).

Figure 10 is a photomicrograph at 50 times magnification of the surface of an alumina grit blasted aluminum instrument handle.

Figure 11 is a photomicrograph at 200 times magnification of the surface of a water jet blasted aluminum disc (A-7).

Figure 12 is a photomicrograph at 200 times magnification of the surface of an alumina grit blasted aluminum instrument handle.

Figure 13 is a schematic of the equipment used for the invention blasting process.

The roughened surface implants, according to the invention, which are free of particulate debris, are preferably produced by blasting implant surfaces with biocompatible liquids at high pressures. These liquids may further contain soluble, vaporizable, or deliquescable solid particulates. The resultant surfaces are roughened for improved tissue and cell adhesion, and bone cement adhesion, as required. Also, the surfaces may contain residual compressive stresses that enhance the fatigue strength of the implant.

In a preferred embodiment of the methods for producing implants according to the invention, an implant surface is subjected to blasting with pressurized water. The pressure of the water is selected depending upon the hardness of the surface material of the medical implant. Thus, a softer metal, such as aluminum, will require a lower water pressure than a harder metal alloy, such as cobalt-chrome-molybdenum, to produce the same roughness index on the surface. For instance, in order to produce an average surface roughness (R_a) of 250 micro-inches on an aluminum implant surface, the water pressure should range from about 10,000 to about 90,000 psi, if the implant is located 0.5 inches distance from the point at which the water exits a jet tip and the traverse-rate (the speed of travel of the

spray nozzle) is about 4 inches per second. To produce a cobalt-chrome-molybdenum medical implant of the same roughness, the water pressure should range from about 10,000 to about 90,000 psi, and should be located at a distance of 0.5 inches from the tip of the water jet, and the traverse-rate should be about 100 times lower at 0.04 inches per second. The lower traverse-rate permits blasting of the material for longer periods of time and this is essential due to the greater hardness of Co-Cr-Mo compared to aluminum. The same effect can also be produced by using a higher pressure instead of a lower traverse-rate. This can also be achieved by using a shorter working distance (i.e., the distance between the blasting nozzle and the implant).

Implants, according to the invention, may be produced from a wide range of metals and alloys, including such materials as titanium, cobalt, zirconium, tantalum, niobium, nickel, aluminum, and their alloys, as well as stainless steels. Implants, according to the invention, may also be produced from ceramic and plastics. Some of these metals or alloys are harder than others so that blasting parameters should be adjusted to achieve a desired R_a. Therefore, for example, the suitable pressure parameter range can be from about 3,000 psi to about 90,000 psi. The desired R_a is one such that the roughness is high enough to promote attachment of tissue, bone, cells, or bone cement, but low enough to minimize adverse effects on wear and fatigue strength.

One of the blasting parameters that may be varied, according to the invention, is the density of the liquid biocompatible blasting medium. Thus, denser liquids have higher impact on the implant surface and hence are more effective at roughening harder surfaces.

The average surface roughness (R_a) and the topography of the roughened surface may be altered by a judicious selection of operating variables in the hydroblaster. These variables include but are not limited to the blasting pressure, duration of blasting, distance of blasting nozzle from implant surface, the number of blasting passes over a given area, the configuration of the jet-spray (e.g., fan type or orifice type). In the event that particulates are included in the blasting medium to assist in imparting residual compressive stresses to the surface and/or to roughen the surface, then further operating variables such as the size, shape and hardness of the particles used also have a significant effect on the topography of the roughened surface produced. Thus, for instance, particles of larger size and higher hardness will tend to produce greater surface roughening as well as higher residual compressive stresses. More spherical particles would tend to cause less surface roughening and higher residual compressive stresses. Denser particles, which would tend to resist fragmentation, would also have the same effect.

Blasting with either biocompatible liquids or solid particulates in a fluid carrier medium may be accomplished using many different types of spray nozzles, depending upon the type of surface desired. A 0° orifice nozzle directs a stream of the blasting medium at a small area of the workpiece. A 15° fan nozzle directs a fan-type spray of the blasting medium over a larger area of the workpiece. Other types of spray patterns can also be produced by judicious selection of the blasting nozzle. The nozzles may be rotated continuously about their own axis to convert a fan-shaped spray to a cone-shaped spray. The workpiece and/or the spray gun may be subjected to translation, revolution or rotation to ensure uniform blasting of different areas of the workpiece. The spray-gun may be moved horizontally, vertically, or both (to produce a cross-hatch pattern).

The degree and nature of surface roughening produced by the blasting process is measured by a number of parameters. The most commonly used parameter is the average surface roughness, R_a. This is a measure of the arithmetic average deviation of the roughness profile from its mean line. Thus this parameter gives equal weight to peaks as well as valleys on the surface. The reduced peak height, R_{pk}, is a parameter which is a measure of the number and height of the peaks on the surface. Reduced valley depth, R_{vk}, is a measure of the number and depth of the valleys on the surface.

The following examples are illustrative of the invention and are not intended to limit the scope of the invention as described above and claimed hereafter.

Example 1

Three materials commonly used in medical implants, wrought (ASTM F 799) cobalt-chrome-molybdenum, Ti-6Al-4V, and aluminum, were selected for subjecting to blasting using various combinations of blasting media and blasting parameters. The hardness of these materials were as follows:

Material		Hardness (VHN)
Aluminum		107
Ti-6Al-4V		370
Cobalt-Chrome-Molybdenum	(ASTM F 799)	465

(where VHN stands for Vickers Hardness Number)

Disc specimens of each of these materials were blasted at a pressure of 10,000 psi with water as a carrier including salt particles. Other specimens were hydroblasted with water only at a pressure of 36,000 psi. The results are as shown in Table 1.

TABLE 1

Specimen No.	Specimen Material	Water Pressure (psi)	Media Used	Traverse Rate (ips)	No. of Passes	Avg. Surface Roughness (R_a) (micro inches)	Reduced Peak Height (R_{pk}) (micro inches)	Reduced Valley Depth (R_{vk}) (micro inches)
A-2	Aluminum	10000	salt	**	**	244	222	896
A-3	"	10000	salt	**	**	96	92	459
A-4	"	36000	none	0.1	1	816	172	1126
A-5	"	36000	none	1	1	663	352	154
A-6	"	36000	none	2	1	322	332	540
A-7	"	36000	none	4	1	257	389	228
T-2	Ti-6Al-4V	10000	salt	**	**	33	51	92
T-3	"	10000	salt	**	**	71	14	42
T-4	"	36000	none	0.1	1	203	274	336
T-5	"	36000	none	0.25	1	193	140	380
T-7	"	36000	none	0.33	1	211	143	412
T-8	"	36000	none	0.4	1	105	23	437
T-9	"	36000	none	1	1	43	34	31
C-5	ASTM F799 Co-Cr-Mo	36000	none	0.04	1	93	33	516
C-6	"	36000	none	0.04	2	244	178	455
C-7	"	36000	none	0.04	3	233	241	525

The salt used here is sodium chloride.

** Manual Operation, process parameters do not apply

Note: All tests used a 15° fan jet spray nozzle and a 0.5 inch working

distance. All roughness measurements (R_a, R_{pk}, and R_{vk}) were performed using a profilometry trace perpendicular to the direction of travel of the blasting nozzle. The following equipment settings were used: Trace Length = 0.050 inch, Cut-off Length = 0.030 inch, Tracing Speed = 0.012 inch/sec., Phase Correction Filter Activated.

A roughened surface for enhancement of cement or bone attachment was achieved on an aluminum specimen by blasting with salt using water as the carrier medium at 10,000 psi. The roughness (R_a) of the surface was 244 micro inches. However, under the same conditions, surface roughness of the Ti-6Al-4V specimens (T-2 and T-3)were considerably lower due to the greater hardness of this material relative to aluminum. It is expected that even higher pressures or harder blasting media would be required to produce a comparable surface roughness on cobalt-chrome-molybdenum disks, which have considerably harder surfaces.

Blasting with water alone was effective to produce an average roughness (R_a) of 257 micro inches on the aluminum specimen A-7 using a spray nozzle travel speed of 4.0 inches per second. Lower traverse-rates produced even higher surface roughness values. Since increased roughness tends to cause reduction in fatigue strength, process parameters may be adjusted to insure that the surface produced is not so rough as to cause an unacceptable reduction in fatigue strength in the implant.

Blasting with water at 36,000 psi, without salt, was effective in producing a surface roughness (R_a) of 203 micro-inches on a Ti-6Al-4V specimen, T-4. The higher pressure was achievable due to the smaller nozzle useable in the absence of solid blasting media.

Even for the cobalt-chrome-molybdenum disks, which have a high hardness, (465 VHN), blasting with water produced an average roughness (R_a) of 233 micro-inches and 244 micro-inches respectively on specimens C-6 and C-7. However, to achieve this roughness, a traverse-rate of 0.04 inch per second was required, along with 2-3 passes of the spray over the surface.

The equipment used for the water-jet blasting, as well as the salt and water blasting described in Table 1, was manufactured by National Liquid Blasting, Wixom, MI. A schematic of the equipment is shown in Figure 13. The equipment includes: a Z-axis adjustable blasting nozzle (2); a X-axis, Y-axis, and rotational fixturing (3); a sonic insulated stainless steel blasting enclosure (4); controls for high pressure liquid supply and position, speed and traverse-rate movements for X-, Y- and Z-axes as well as rotation (5); a regulated high pressure water supply (6); an electric motor driven pump and high pressure manifold (7); and a filtered tap water inlet (8). The working distance (9), the distance between the top surface of the workpiece (1) and the nozzle tip, is typically 0.25 inches with a #5 nozzle.

Photomicrographs, at various magnifications, were taken of specimens tabulated in Table 1 for comparison with alumina grit blasted surfaces produced by prior art methods. Thus, Figures 1 and 3 are photomicrographs of specimen C-7 that may be compared with alumina grit blasted cobalt-chrome-molybdenum shown in Figures 2 and 4. Likewise, Figures 5 and 7 are photomicrographs of the surface of specimen T-4 for comparison with alumina grit blasted Ti-6Al-4V shown in Figures 6 and 8. Figures 9 and 11 are photomicrographs of the surface of specimen A-7 for comparison with alumina grit blasted aluminum surfaces shown in Figures 10 and 12. The roughness

values of the alumina grit blasted devices were also measured using the same measurement parameters and are given below:

Table 2

Specimen Material	Average Roughness R_a (micro inches)	Reduced Peak Height R_{pk} (micro inches)	Reduced Valley Depth (R_{vk}) (micro inches)
Aluminum	244	252	576
Ti-6Al-4V	250	231	498
Cast Co-Cr-Mo (ASTM F 75)	161	304	351
Cast Co-Cr-Mo (F 75)	221	295	108
Cast Co-Cr-Mo (F 75)	256	257	206
Cast Co-Cr-Mo (F 75)	285	169	517
Wrought Co-Cr-Mo (ASTM F 799)	196	356	383

Example 2

Cylindrical rods of wrought (ASTM F 799) Co-Cr-Mo alloy were subjected to water-jet blasting with a 15° fan jet nozzle at a pressure of 36,000 psi, traverse rate of 0.05 inch/sec and a working distance of 0.375 inch, for approximately 15 passes. The rods were rotated at approximately 11 rpm to ensure uniform texturing of the surface. The roughness values of the specimens were determined by profilometry using the following equipment settings: Trace Length = 0.08 inch, Cut-off Length = 0.03 inch, Tracing Speed = 0.012 inch/sec. The rods were subsequently potted in PMMA bone cement, the cement was allowed to set, and the force required to remove the rods from the cement was

measured.

Similar Co-Cr-Mo rods were also subjected to standard alumina grit-blasting, using prior art methods, and their roughness values and cement attachment strength determined, as described above. The results of both sets of tests are given in Table 3.

Table 3

Blasting Medium	Avg. surface roughness, R_a (micro-inches)	Reduced peak height, R_{pk} (micro-inches)	Reduced valley depth, R_{vk} (micro-inches)	Cement Attachment Strength (psi)
Water-jet	166	96	205	1595
Water-jet	176	130	408	1780
Water-jet	191	70	365	1695
Water-jet	221	156	346	2027
Water-jet	227	163	342	1760
Average	196±27	123±40	333±76	1771±160
Alumina Grit	151	272	322	1214
Alumina Grit	154	178	199	1225
Alumina Grit	167	161	202	1255
Alumina Grit	187	284	273	1300
Alumina Grit	149	146	319	1126
Average	162±16	208±65	263±60	1224±64

As shown in the Table, water-jet blasting using the process parameters described above produced a slightly higher cement attachment strength compared to prior art alumina grit blasting. While

not wishing to be bound by any theory, the inventors offer the following explanation of this phenomenon. Under certain sets of blasting conditions, the water-jet blasting process can produce smaller, more rounded peaks (smaller Rpk) and larger valleys (greater Rvk) compared to standard grit-blasting, although the overall surface roughness (Ra) may be comparable. This can potentially lead to higher cement attachment strength for water-jet blasted implants, compared to prior-art alumina grit-blasted implants.

Having described the invention above, various modifications of the techniques, procedures, material and equipment will be apparent to those in the art. It is intended that all such variations within the scope and spirit of the appended claims be embraced thereby.

CLAIMS

1. A method of producing a medical implant comprising the step of:

blasting at least a portion of an outer surface of the implant with a medium comprising a biocompatible liquid.

2. The medical implant of claim 1 with a roughened surface suitable for attachment of tissue, bone, cells or bone cement.

3. The medical implant of claim 1 for use where an outer surface of the implant is subject to fatigue.

4. The method of claim 1, wherein the step of blasting is performed at a pressure of about 36,000 psi.

5. The method of claim 1 or 4 wherein the step of blasting is sufficient to roughen the surfaces to an average surface roughness of from about 150 micro-inches to about 300 micro-inches.

6. The method of claim 1 or 4 wherein the step of blasting is performed with a medium that further comprises biocompatible solid particulates.

7. The method of claim 6, wherein the step of blasting includes using biocompatible solid particulates selected from the group consisting of soluble biocompatible solids, deliquescable biocompatible solids, sublimatable biocompatible solids and vaporizable biocompatible solids.

8. The method of claim 6, wherein the step of blasting is performed with a biocompatible solid that is a soluble salt.

9. The method of claim 6, further comprising a step of removing substantially all blasting residue.

10. The method of claim 9, wherein the step of removing blasting residue is performed by a method selected from the group consisting of ultrasonic cleaning, flushing with a biocompatible medium, sublimating said blasting residue and vaporizing said blasting residue.

11. The medical implant of claim 1 wherein the implant is made of metal.

12. The medical implant of claim 1 wherein the implant is made of a metal alloy.

13. The medical implant of claim 1, wherein the implant is made of ceramic material.

14. The medical implant of claim 1, wherein the implant is made of polymeric mateiral.

15. The medical implant of claim 3 comprising a cold worked surface with residual compressive stresses therein.

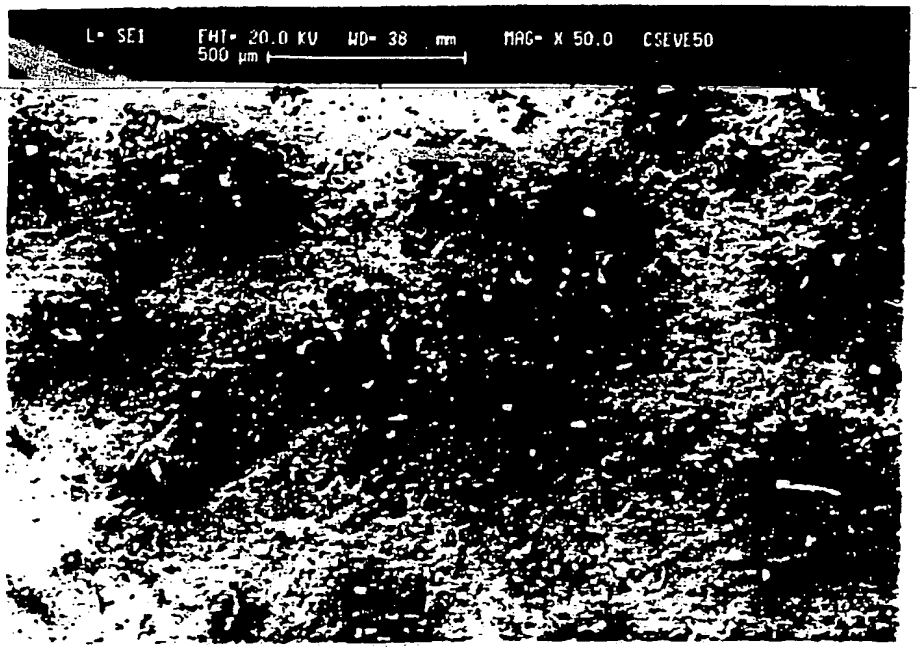
16. The medical implant of claim 1 suitable for attachment of tissue, bone, cells or bone cement and for use where an outer surface of the implant is subject to fatigue.

17. A method of producing a medical implant with enhanced fatigue strength, the method comprising the step of:

blasting at least a portion of an outer surface of the implant with a medium comprising a biocompatible liquid at a pressure sufficient to provide residual compressive stresses therein.

18. A medical implant adapted for attachment thereto of cells, bone, tissue or bone cement, the medical implant comprising:

a roughened outer surface having sufficient surface roughness for attachment, wherein said roughness was produced by a process comprising the steps of (a) blasting at least a portion of the outer surfaces of the implant with a medium comprising a biocompatible liquid at a pressure sufficient to roughen the surfaces, and (b) removing substantially all embedded or attached particulate debris from the blasting process used to roughen the surface.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500 µm

FIG. 1

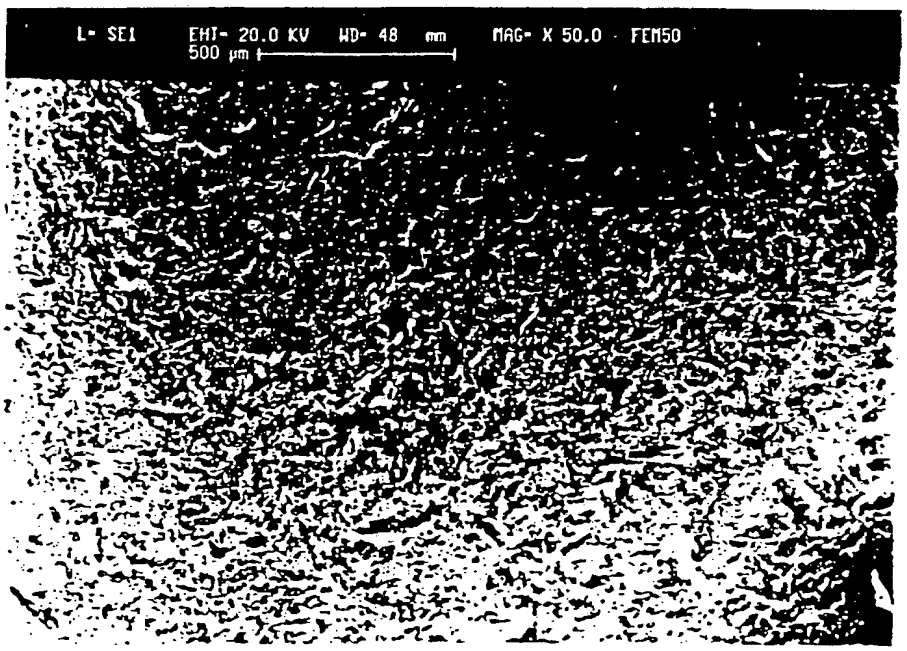
L= SE1 EHT= 20.0 KV WD= 48 mm MAG= X 50.0 FEM50
500 µm

FIG 2

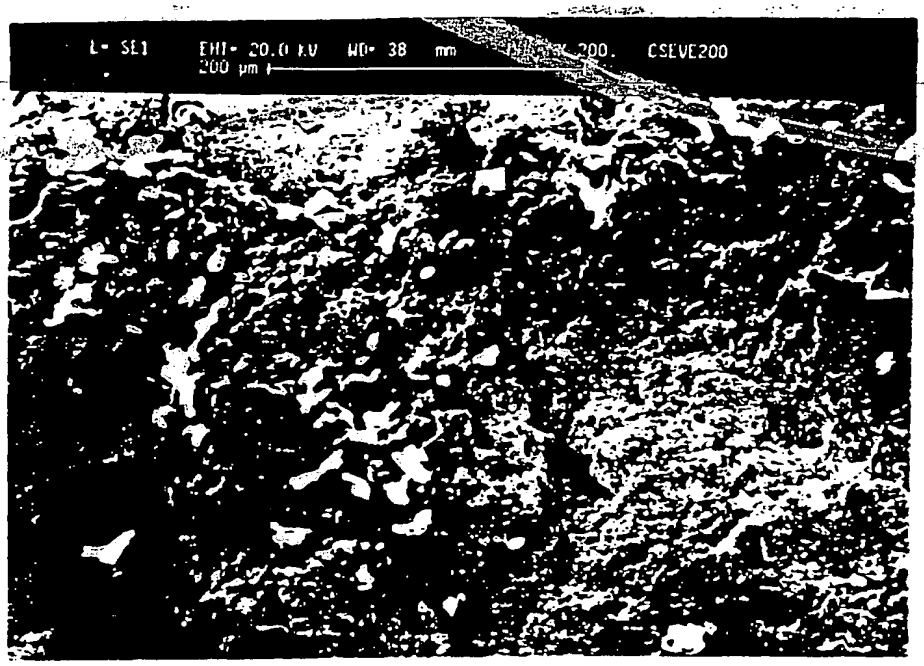
L= SE1
EHT= 20.0 KV
WD= 38 mm
200 µm
200. CSEVE200

FIG. 3

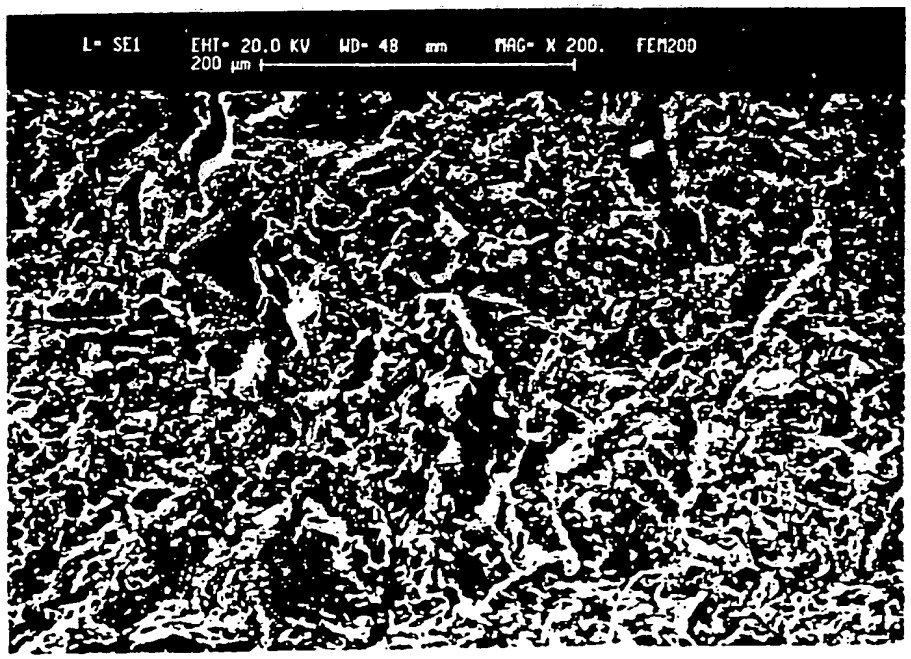
L= SE1
EHT= 20.0 KV
WD= 48 mm
MAG= X 200.
200 µm
FEM200

FIG. 4

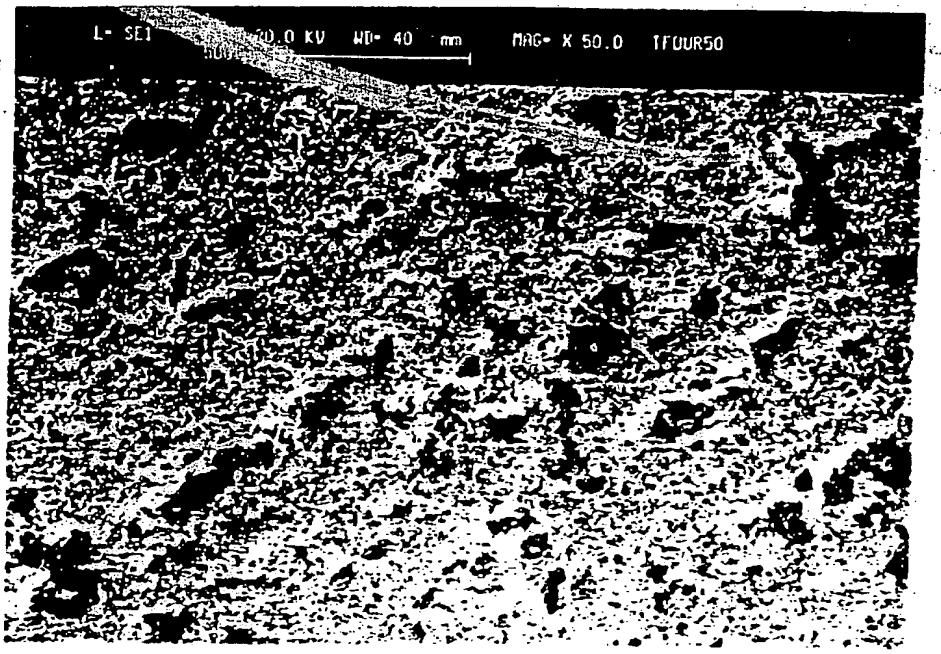
L= SE1
20.0 KV WD= 40 mm
MAG= X 50.0 TFOUR50

FIG. 5

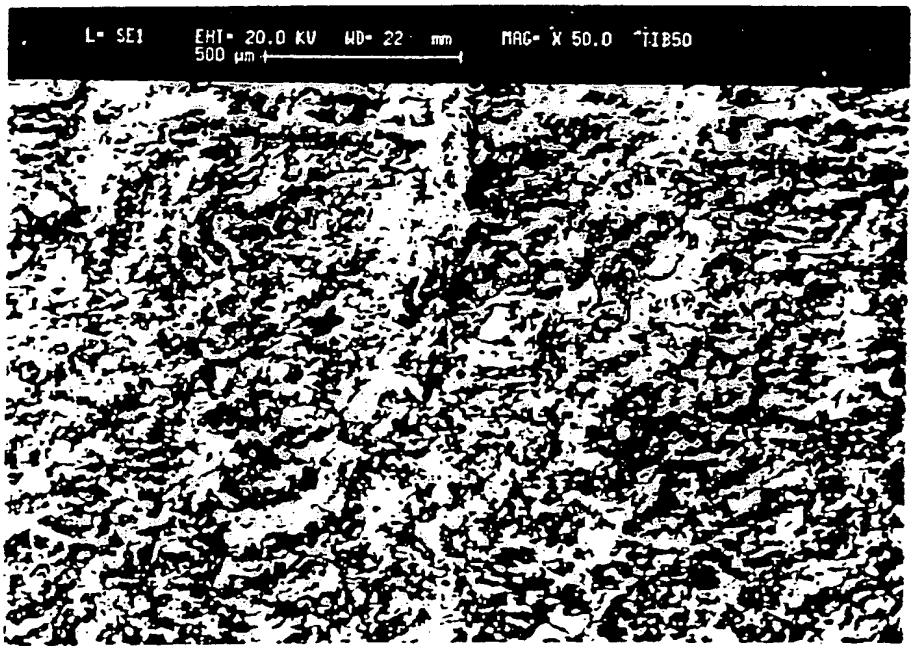
L= SE1
EHT= 20.0 KV WD= 22 mm
500 µm
MAG= X 50.0 TIB50

FIG 6

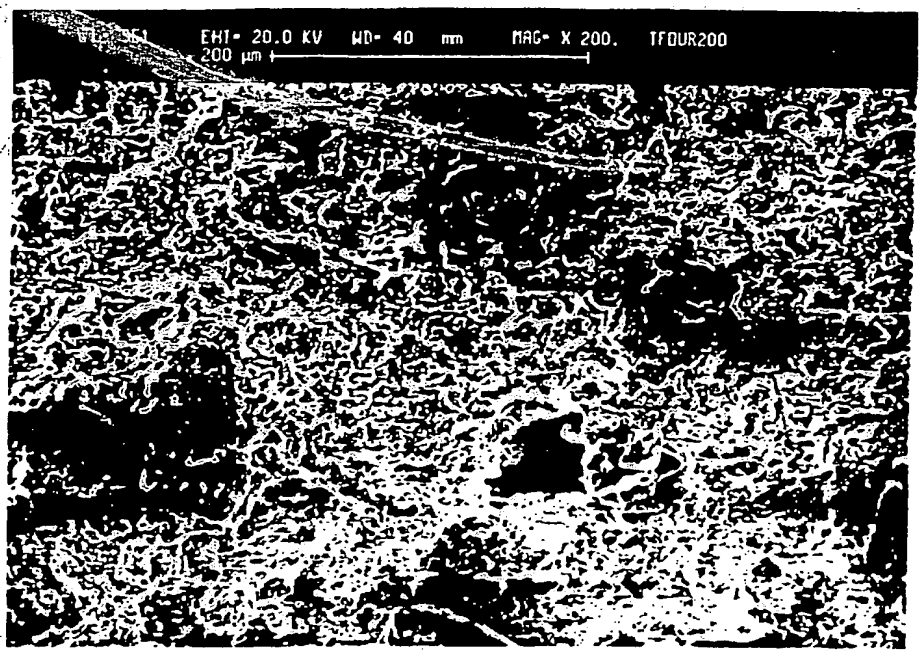
EHT= 20.0 KV WD= 40 mm MAG= X 200. TFOUR200
200 µm

FIG. 7

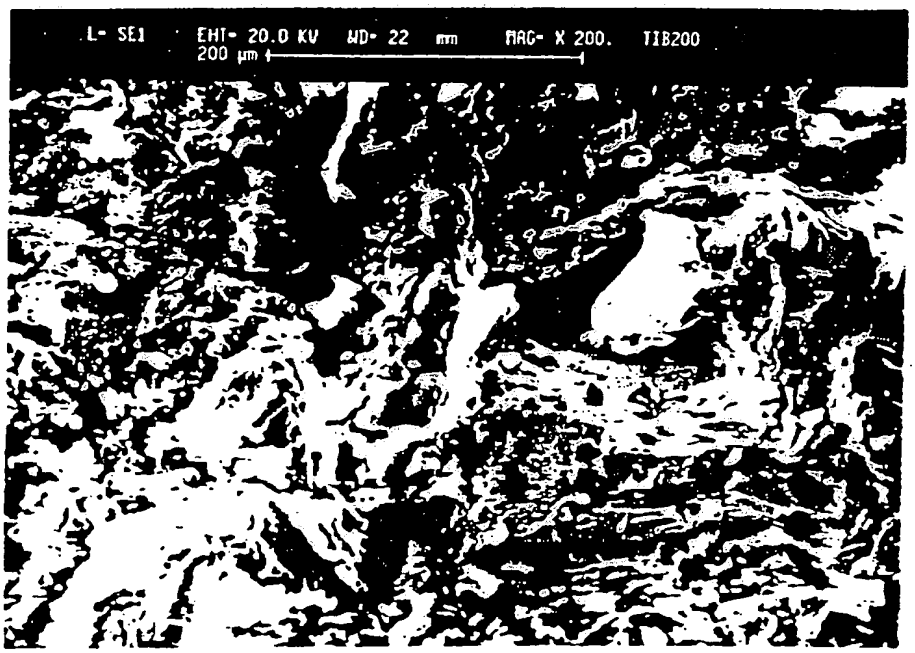
L= SE1 EHT= 20.0 KV WD= 22 mm MAG= X 200. TIB200
200 µm

FIG 8

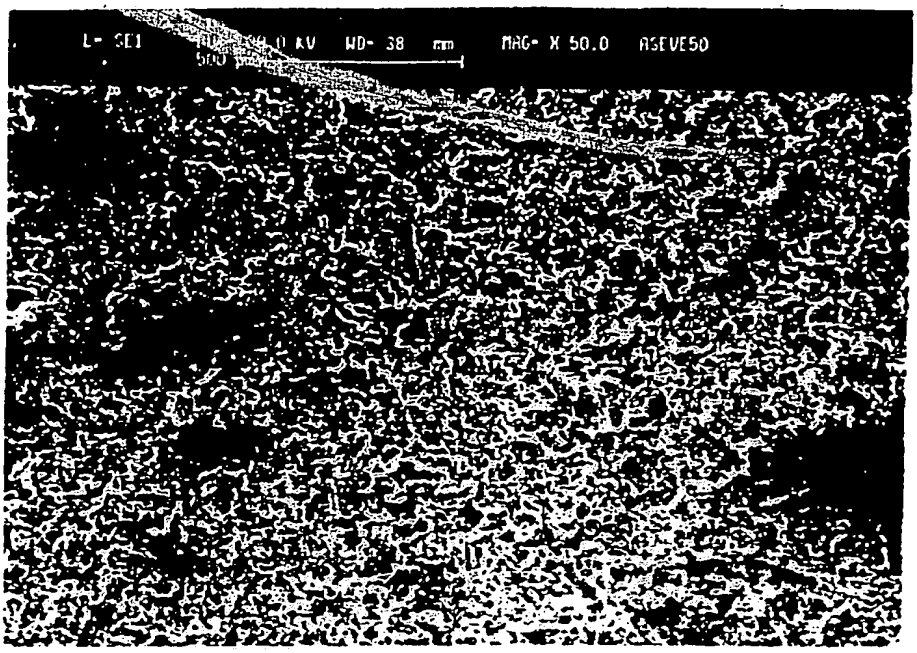
L= SE1
WD= 38 mm
MAG= X 50.0 ASEVE50

FIG. 9

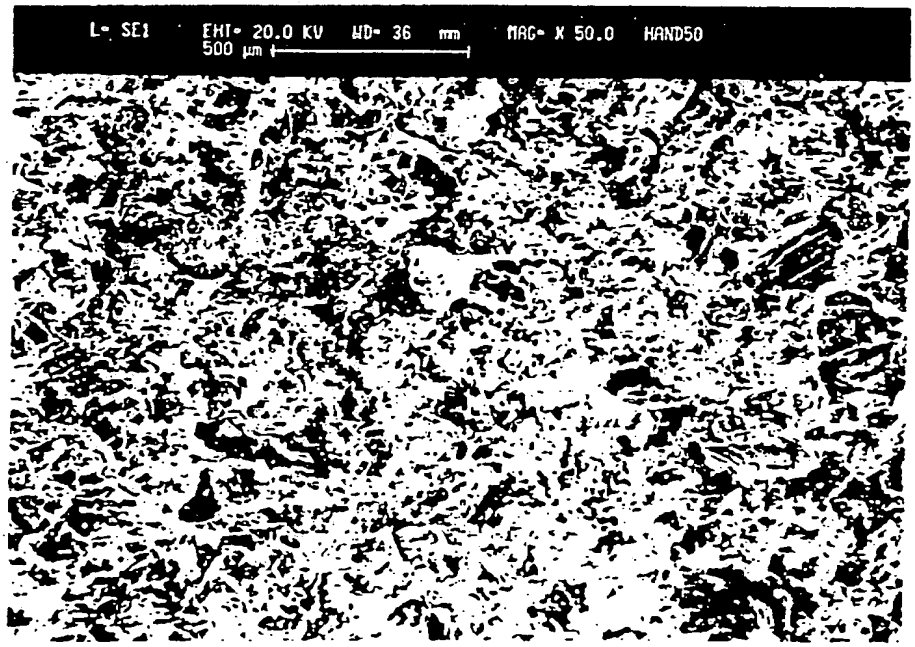
L= SE1
EHT= 20.0 KV
WD= 36 mm
500 µm
MAG= X 50.0 HAND50

FIG 10

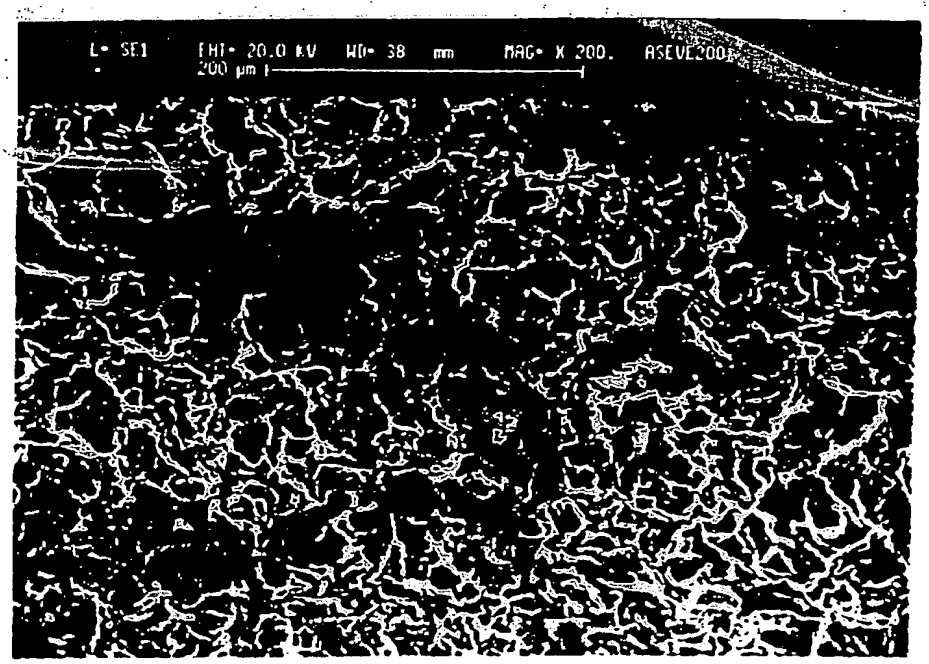
L= SE1 EHT= 20.0 KV WD= 38 mm MAG= X 200. ASEVE200
200 µm

FIG. 11

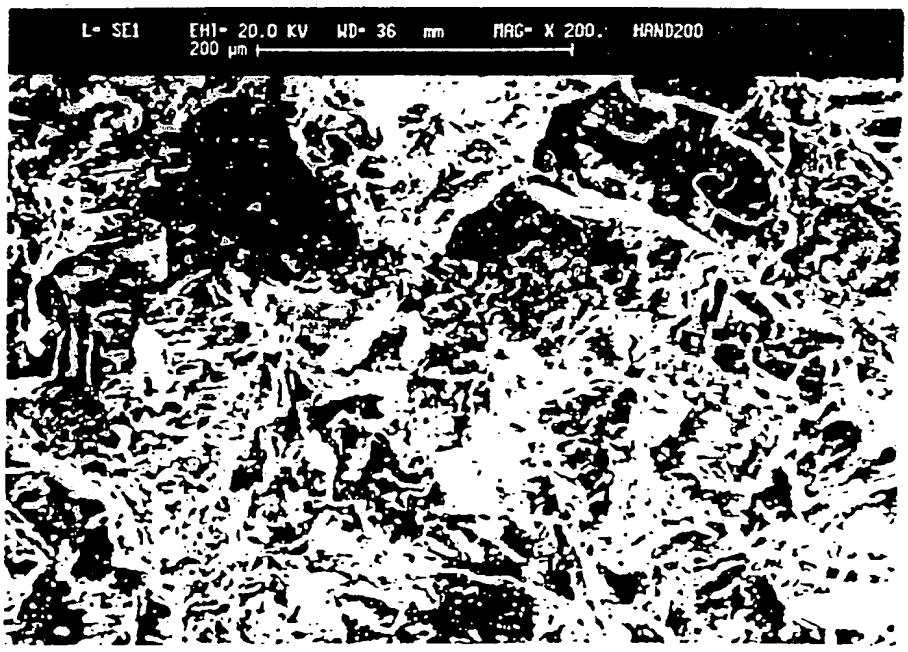
L= SE1 EHT= 20.0 KV WD= 36 mm MAG= X 200. HAND200
200 µm

FIG. 12

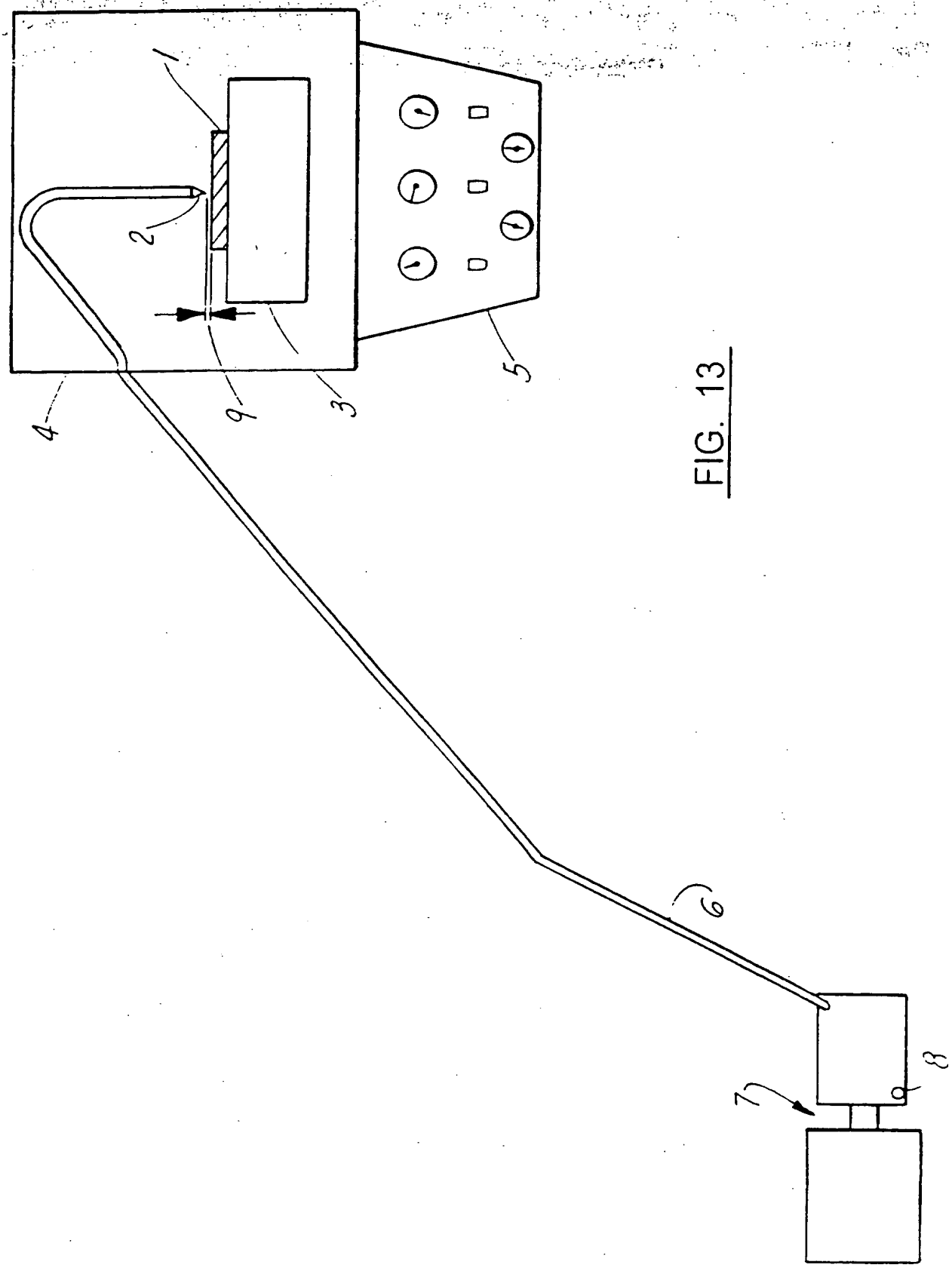

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/03619

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/28
US CL : 623/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/433, 423; 433/201.1; 623/11, 16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,236,459 (KOCH ET AL.) 17 August 1993, see the entire document.	1-7, 11, 13, 14, 16-18 --- 8-10, 12, 18
Y	US, A, 5,317,841 (COOK ET AL.) 07 June 1994, see the entire document.	8-10
Y	US, A, 5,057,108 (SHETTY ET AL.) 15 October 1991, see the entire document.	12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 APRIL 1996	Date of mailing of the international search report 10 MAY 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305 3230	Authorized officer PAUL PREBILIC Telephone No. (703) 308-0858

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